DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of copolymer I (group I) and Huntington's disease (group II) in the reply filed on 8/5/2009 is acknowledged. The traversal is on the ground(s) that the requirement is impermissible as to the type of neurodegenerative disease in the independent claims, and referred to M.P.E.P. §1893.03(d). This is not found persuasive because the requirement is based on Markush type of species disclosed in the claims, rather than Groups of inventions of different categories of claims (i.e. product, process or apparatus, etc.). M.P.E.P. §1893.03(d) is mainly applicable when claims are directed to multiple categories of inventions. With a Markush type species, Applicant's attention is directed to M.P.E.P. §1850(III)(B).

M.P.E.P. §1850 states 'the situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature. When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(B) (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.

In paragraph (B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved. The fact that the alternatives of a Markush grouping can be differently classified should not, taken alone, be considered to be justification for a finding of a lack of unity of invention.

Thus, the species listed in the claims do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species do not share the significant structural element or fall into a recognized class of chemical compounds, thus the species lack unity of invention.

The species disclosed are not considered as art-recognized equivalents each other. The species are copolymer I, copolymer I-related peptide, copolymer I-related polypeptide, and T cells activated with the above species. While copolymer I-related peptide and copolymer I-related polypeptide might be considered to be equivalent, at least, copolymer I and T cells, or copolymer I-related peptide and T cells are not equivalent each other.

Furthermore, the Examiner disagrees with the conclusion of applicant that the diseases disclosed in claim 25 are art-recognized equivalents. It is well known that these are considered as neurodegenerative diseases, however, the characteristics of each disease disclosed are known to be different, and cannot be considered as equivalent each other.

As indicated in the previous OA, upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claims as provided by 37 C.F.R. 1.141.

The requirement is still deemed proper and is therefore made FINAL.

Claims 27, 28, 31 and 33 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 24-26, 30, 32 and 34-37 have been considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-26, 30, 32 and 34-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating neuronal degeneration caused by

glutamate toxicity or $A\beta_{1-40}$ toxicity in an animal model, does not reasonably provide enablement for treating or reducing progression a neurodegenerative disease such as Huntington's disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQd 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

The instant claims disclose a method of treating a neurodegenerative disorder or disease having accumulation of misfolded and/or aggregated proteins except prion-related diseases by administering Copolymer I to an individual suffering from the diseases or disorders; the claimed method are also for reducing progression, for protection from neurodegeneration, for protection from glutamate toxicity.

The specification discloses examples and evidence showing that administration of Cop I reduced glutamate toxicity or $A\beta_{1-40}$ toxicity in retinal ganglion cells in an animal model or (see Figures 1-9, 14 and Brief Description of the Figures at p.9-13). These descriptions are based on the animal model having been injected or immunized prior to glutamate toxicity or $A\beta_{1-40}$ toxicity.

However, the specification does not provide enabling embodiment showing that the administration or immunization of an individual suffering a neurodegenerative disease or disorder having accumulation of misfolded proteins or aggregates, particularly, Huntington's disease (HD) with Cop I.

The state of the art is relatively low with regard to the treatment of HD. Despite extensive research activity in the art, the state of the art with regard to treating these conditions broadly is underdeveloped. In particular, there is no known agent that is effective in treating these diseases. According to the article on HD from National Institute of Neurological Disorders and Stroke, a number of medications available to help control emotional and movement problems associated with HD, but there is no treatment to stop or reverse the course of the disease (p.6).

The specification discloses that the etiology differs among neurodegenerative diseases, the propagation steps are similar, and cytotoxicity caused by excitatory amino acids, free radicals and nitric oxide is common to all the neurodegenerative disorders (p.4, lines 5-9), and glutamate is one of the most common mediators of toxicity (p.4, lines 10-16).

Applicant's limited disclosure based on animal model in glutamate toxicity is noted but is not sufficient to justify claiming a method of treatment for HD broadly.

The neurodegenerative diseases treatment art involves a very high level of unpredictability. The lack of significant guidance from the present specification or prior art with regard to the actual treatment of HD in a human subject with the claimed active ingredient makes practicing the claimed invention unpredictable.

Absent a reasonable *a priori* expectation of success for using a specific agent or combination of agents to treat these neurodegenerative diseases, one skilled in the art would have

to extensively test many various patients in many various stages of the disease. Since each prospective embodiment, and indeed future embodiments as the art progresses, would have to be empirically tested, and those which initially failed tested further, an undue amount of experimentation would be required to practice the invention as its is claimed in its current scope, because the specification provides inadequate guidance to do otherwise.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24-26, 30, 32 and 34-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Eisenbach-Schwartz et al. (US 2002/0037848).

Eisenbach-Schwartz et al. teach a method of administering or immunizing copolymer I (or Cop I) to a patient suffering neurodegenerative diseases such as Huntington's disease, and reducing or protecting glutamate toxicity (see entire document; esp. Abstract; par. 26, 97 and 116).

Thus, the reference anticipates the claimed subject matter.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAEYOON KIM whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/
Primary Examiner, Art Unit 1651